

CLAIMS

I Claim:

1. An air introduction device for use in anastomotic leak testing, comprising:
a unitary, elastomeric body defining an interior space and having a proximal portion
5 adapted to be inserted into an anus of a person such that said proximal portion causes the anus to constrict around said proximal portion and thereby seal said proximal portion against the anal wall, a distal portion adapted to mate with a pumping device to enable air to be directed from the pumping device into and through said body and an expanded portion having a larger size than said proximal portion and interposed between said proximal portion and said distal portion, said
10 expanded portion being adapted to engage with an anal opening to limit insertion of said proximal portion into the anus and seal said body against the anal opening.

2. The air introduction device of claim 1, wherein said proximal portion includes a rounded or tapered tip to facilitate insertion of said proximal portion into the anus.
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3. The air introduction device of claim 1, wherein said expanded portion includes a first truncated conical surface tapering from a circumferential portion having a largest diameter of said expanded portion to said proximal portion and a second truncated conical surface tapering from said largest diameter circumferential portion of said expanded portion to said distal portion.
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4. The air introduction device of claim 1, wherein said distal portion defines a lumen adapted to receive a connector of an insufflation bulb.

5. The air introduction device of claim 1, wherein said body is substantially tubular,
25 said proximal portion being defined by a wall having an outer diameter of about 1.062 inches, said expanded portion being defined by a wall having a maximum outer diameter of about 1.75 inches and said distal portion being defined by a wall having an inner diameter of about 0.375 inches.

6. The air introduction device of claim 1, wherein said distal portion has first and second arms, said first arm defining a first lumen adapted to receive a connector of an insufflation bulb, said second arm defining a second lumen and having a closed distal end, said second lumen being adapted to receive a visualization device when said distal end is opened.

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7. The air introduction device of claim 6, wherein said second arm includes a constriction between said second lumen and said interior space of said body.

8. The air introduction device of claim 6, wherein said proximal portion and said 10 expanded portion have a common central axis and said second arm of said distal portion has a central axis parallel to and offset from said common central axis of said proximal portion and said expanded portion.

9. The air introduction device of claim 1, wherein said distal portion has first and 15 second arms, said first arm defining a first lumen adapted to receive a connector of an insufflation bulb, said second arm defining a second lumen, further comprising a pressure relief valve arranged in said second lumen for releasing air when a specific air pressure in the rectum is reached.

20 10. The air introduction device of claim 9, further comprising signal means coupled to said second side arm for providing a signal when air is released via said valve.

11. The air introduction device of claim 10, wherein said signal means comprise a 25 bill-shaped extension attached to said second arm and having at least one flap arranged to vibrate and produce an audible signal when air is released via said valve.

12. The air introduction device of claim 1, wherein said distal portion has first and second arms, said first arm defining a first lumen adapted to receive a connector of an insufflation bulb, said second arm defining a second lumen, further comprising a bill-shaped

extension attached to said second arm and having at least one flap arranged to vibrate and produce an audible signal when air passes through, and which air will pass through only when a specific air pressure is reached within the rectum.

5 13. An air introduction device for use in anastomotic leak testing, comprising
a unitary body defining an interior space and comprising
insertion and sealing means for enabling insertion of a part of said body into an
anus of a person such that the anus constricts around said part and thereby seals said body against
the anal wall,

10 insertion-limiting means for limiting insertion of said part of said body into the
anus and occluding an opening of the anus, and
coupling means for enabling coupling of said body to an insufflation bulb such
that air is directable from the insufflation bulb through said coupling means into said interior
space in said body.

15 14. The air introduction device of claim 13, wherein said insertion and sealing means
enable insertion of a proximal portion of said body into the anus.

20 15. The air introduction device of claim 14, wherein said body is substantially tubular
and said insertion-limiting means comprise an expanded portion of said body arranged behind
said proximal portion and having a larger diameter than said proximal portion, said expanded
portion being adapted to engage with the anal opening to limit insertion of said proximal portion
into the anus and seal said body against the anal opening.

25 16. The air introduction device of claim 14, wherein said proximal portion includes a
rounded tip to facilitate insertion of said proximal portion into the anus.

17. The air introduction device of claim 13, wherein said coupling means comprise a
first lumen arranged on a distal portion of said body and adapted to receive a connector of the

insufflation bulb.

18. The air introduction device of claim 17, wherein said distal portion has first and second arms, said first arm defining said first lumen, said second arm defining a second lumen 5 and having a closed distal end, said second lumen being adapted to receive a visualization device when said distal end is opened.

19. The air introduction device of claim 17, wherein said distal portion has first and second arms, said first arm defining said first lumen, said second arm defining a second lumen, 10 further comprising a pressure relief valve arranged in said second lumen for releasing air when a specific air pressure in the rectum is reached.

20. The air introduction device of claim 19, further comprising signal means coupled to said valve for providing a signal when air is released via said valve.

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21. The air introduction device of claim 20, wherein said signal means comprise a bill-shaped extension attached to said second arm and having at least one flap arranged to vibrate and produce an audible signal when air is released via said valve.

20 22. The air introduction device of claim 17 wherein said distal portion has first and second arms, said first arm defining first lumen, said second arm defining a second lumen, further comprising a bill shaped extension attached to said second arm and having at least one flap arranged to vibrate and produce an audible signal when air passes through, and which air will pass through only when a specific air pressure is reached within the rectum.

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23. A method for anastomotic leak testing, comprising the steps of: providing a unitary body defining an interior space and having a proximal portion, a distal portion and an expanded portion interposed between said proximal portion and said distal portion;

coupling an insufflation bulb to the distal portion of the body;

inserting the proximal portion of the body into the anus of a patient to cause the proximal portion to dilate the anus whereby the anus constricts around the proximal portion and a seal is formed between the proximal portion and the wall of the anus and the expanded portion presses

5 against the opening of the anus to prevent the escape of air from the rectum;

filling the pelvis of the patient with fluid;

occluding the bowel proximal to the anastomosis;

compressing the insufflation bulb to distend the rectum of the patient with air; and

10 checking for anastomotic leaks based on the presence of air bubbles in the pelvic fluid

10 once the rectum is sufficiently distended with air.

24. The method of claim 23, further comprising the steps of:

detaching the insufflation bulb from the body after checking for anastomotic leaks while the proximal portion of the body remains inserted in the anus thereby allowing air from the

15 rectum to escape from the rectum and the rectum to deflate; and

then removing the body from the anus.

25. The method of claim 23, wherein the distal portion has first and second arms, the first arm defining a first lumen and the second arm defining a second lumen and having a closed

20 distal end, the insufflation bulb being received in the first lumen.

26. The method of claim 25, further comprising the steps of:

removing the body from the anus after checking for anastomotic leaks based on the presence of air bubbles in the pelvic fluid once;

25 severing the closed end of the second arm;

inserting an endoscope into the second lumen so that a tip of the endoscope sits within a space of the body;

coupling the endoscope to a light source and a camera coupled to a video display;

inserting the proximal portion of the body into the anus;

compressing the insufflation bulb to distend the rectum of the patient with air; and visually inspecting the anastomosis by advancing the tip of the endoscope from the space in the body into the rectum until the anastomosis is viewable through the endoscope to thereby enable the integrity of the anastomosis to be ascertained.

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27. The method of claim 26, further comprising the step of rotating the endoscope to view the entire anastomosis.

28. The method of claim 26, further comprising the step of removing the endoscope 10 from the body when the visual inspection is complete while the body is engaged with the anus and then deflating the rectum removing the body out of engagement with the anus.

29. The method of claim 23, wherein the distal portion has first and second arms, the first arm defining a first lumen and the second arm defining a second lumen, the insufflation bulb 15 being received in the first lumen, further comprising the steps of:
arranging a pressure relief valve in the second lumen to allow air to escape from the rectum when a specific air pressure within the rectum is reached.

30. The method of claim 29, further comprising the step of providing a signal when 20 air is released via the valve.

31. The method of claim 30, wherein the step of providing a signal when air is released via the valve comprises the step of attaching bill-shaped extension having at least one flap to the second arm, the at least one flap being arranged to vibrate and produce an audible 25 signal when air is released via the valve.

32. The method according to claim 23 wherein the distal portion has first and second arms, the first arm defining a first lumen and the second arm defining a second lumen, the insufflation bulb being received in the first lumen, further comprising the steps of:

attaching a bill shaped extension having two flaps to the second arm, the flaps being arranged to vibrate and produce an audible signal when air passes between them, and whereby air cannot pass between said flaps until the air pressure in the rectum reaches a specific pressure.

5 33. An anastomotic leak tester, comprising:
an insufflation bulb having a compressible central portion, a pair of valves on opposite sides of said central portion and arranged to provide a uni-directional flow of air through said central portion upon intermittent compressing of said central portion, and a connector; and
an air introduction device comprising a unitary, elastomeric body defining an interior
10 space and having a proximal portion adapted to be inserted into an anus of a person such that said proximal portion causes the anus to constrict around said proximal portion and thereby seal said proximal portion against the anal wall, a distal portion arranged to mate with said connector of said insufflation bulb to enable air to be directed from said insufflation bulb into and through said body and an expanded portion having a larger size than said proximal portion and interposed
15 between said proximal portion and said distal portion, said expanded portion being adapted to engage with an anal opening to limit insertion of said proximal portion into the anus and seal said body against the anal opening.